



Food and Drug Administration
10903 New Hampshire Avenue
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March 26, 2014

Dental Direkt GmbH
Mr. Uwe Greitens
Authorized Officer
Industriezentrum 106-108
32139 Spenge
GERMANY

Re: K150196
Trade/Device Name: DD cubeX² and accessories
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: February 23, 2015
Received: February 25, 2015

Dear Mr. Greitens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150196

Device Name: *DD cubeX²* and accessories

Indications for Use:

Dental blanks made from *DD cubeX²* are indicated for crowns, multi-unit bridges (up to a maximum of 3 elements) and inlay bridges. Applications include both, anterior and posterior bridges.

Prescription Use **X**

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: **K150196**

510(k) Summary

Submitter of 510 (k)	Dental Direkt GmbH Industriezentrum 106-108 32139 Spenge / Germany
Contact Person	U. Greitens, Authorized Officer Phone: +49 5225 86319-0 / Fax: +49 5225 86319-99
Establishment Registration Number	3008347275
Date Prepared	January 2015
Trade Name of Device	<i>DD cubeX² and accessories</i>
Common Name	Powder, Porcelain
Classification Name	Porcelain powder for clinical use
Regulation Number	21 CFR 872.6660
Product Code	EIH
Panel	Dental
Classification	Class II
Name of legally marketed device	<i>DD Bio Z-transpa (K093748)</i>
Indications for Use	Dental blanks made from <i>DD cubeX²</i> are indicated for crowns, multi-unit bridges (up to a maximum of three elements) and inlay bridges. Applications include both, anterior and posterior bridges.
Device Description	<i>DD cubeX²</i> is a semi-finished dental blank made of yttrium stabilized pre-sintered zirconium dioxide, which has a super high translucency. The ceramics is of type II (not powder), Class 5 according to DIN EN ISO 6872 (FDA Recognition Number 4-178). The <i>DD cubeX²</i> dental blanks are designed for milled production of crowns and bridge frameworks on commercial CAD/CAM systems or hand-operated copy milling machines.

The material is suited ideally for bridges up to 3 elements for both, the anterior and posterior region.
The accessories comprises the *DD Bio ZX² monolith zero*, which is a coloring fluid for zirconia restorations made from yttrium stabilized pre-sintered zirconium dioxide of different degree of translucency.

Comparison of Required Technology Characteristics

The following table shows a summary of the technological characteristics of DD cubeX² (modified product) compared to the predicate (Unmodified product) device.

Comparison of Required Technology Characteristics			
Feature	Unmodified product	Modified product	Comment
Trade name	<i>DD Bio Z-transpa</i>	<i>DD cubeX²</i>	n.a
510(k)	K093748 (Annex 5)	this submission	n.a
Product code	EIH	EIH	Same
Regulatory class	Class II	Class II	Same
Manufacturer	Dental Direkt GmbH former Dental Direkt of America UG (haftungsbeschränkt)	Dental Direkt GmbH	Same
Intended use	Dental blanks made from <i>DD Bio Z transpa</i> are indicated for crowns, multiunit bridges and inlay bridges. Application includes both, anterior and posterior bridges.	Dental blanks made from <i>DD cubeX²</i> are indicated for crowns, multiunit bridges and inlay bridges. Application includes both, anterior and posterior bridges.	Same
Accessories	No	Yes, coloring liquids	This difference offers a better adaptation of dental blank to natural teeth.
Multi-unit bridges	No limitation	Up to a maximum of three elements	Same, if multi-unit bridge has only three elements.
Chemical composition [Units]			
ZrO ₂ + HfO ₂ + Y ₂ O ₃ [wt%]	> 99.0	≥ 99.0	Same
Y ₂ O ₃ [wt%]	5.15 ± 0.20	< 10	Higher amount of Y ₂ O ₃ increases cubic phase in zirconium structure leading to higher translucency.
HfO ₂ [wt%]	< 5	ca. 0.2	Higher purity
Al ₂ O ₃ [wt%]	< 0.1	< 0.1	Same
Other oxides	< 0.2	≤ 0.05	Higher purity

Comparison of Required Technology Characteristics			
Feature	Unmodified product	Modified product	Comment
Categorization ISO 6872	Class 6	Class 5	Class 5 due to restriction to 3-element restorations
Physical characteristics [Units]			
Flexural strength [MPa]	1000 ± 200	> 720	Flexural strength is slightly lower, but higher than required by DIN EN ISO 6872 for Class 5 dental ceramics (> 500 MPa).
E modulus [GPa]	> 210	> 210	Same
Density (after sintering) [g/cm ³]	> 6.0	> 6.0	Same
CTE (25-500 °C) [10 ⁻⁶ K ⁻¹]	11	10	Same
Fracture toughness [MPa * m ^{1/2}]	unknown	4.8	n.a
Physical Testing	Tested according to DIN EN ISO 6872	Tested according to DIN EN ISO 6872	Same (Tests for modified product comprise coloring fluid accessories)
Biocompatibility	EN ISO 10993-1, -5	EN ISO 10993-1, -5,	Same (Tests comprise coloring fluid accessories)

Brief summary

First, DD cubeX² (modified product) shares de facto all product specifications and characteristics of the predicate device (unmodified device). There is no difference in fundamental scientific technology. Secondly, the modification of the material composition results in a higher translucency of the product, which leads to better aesthetic results. However, it also leads to a lower flexural strength when compared to the unmodified product. This is compensated by restricting the use of *DD cubeX²* if used for multi-unit bridges to three element bridges. Finally the Flexural strength testing result of DD cubeX² (modified product) is considerably higher than required by DIN EN ISO 6872 for class 5 dental ceramics indicated for three element bridges including molar restorations. Thirdly, the two devices are similar in physical and mechanical properties. Also both (for DD cubeX² (modified product) including coloring fluid accessories) their safety and effectiveness have been verified by appropriate FDA recognized standards.

Through they are not identical in chemical material composition, such difference will not influence the core usage of the device, thus will not affect the devices` substantial equivalence.

Discussion of Tests Performed

- Clinical Tests

Dental Direkt GmbH did not conduct, nor rely upon, clinical tests to determine substantial equivalence as dental ceramics that fall under FDA product code EIH have a long history of safe and effective use in the US.

- Non Clinical Tests

Non-clinical testing was performed in order to validate the product against the company's specified design requirements, and to evaluate its safety and effectiveness according to the following standards:

- EN ISO 10993-1 (biological compatibility) and EN ISO 10993-5 (cytotoxicity)

With *DD Bio ZX² monolith zero* colored and then sintered *DD cubeX²* finished products were tested by an accredited testing laboratory with respect to biocompatibility. The laboratory certified that "the insolubility is in compliance with the requirements of the Standard. There is no evidence that effects hazardous to the patient will arise by release of leachable ingredients/contaminants". Based on the test results *DD cubeX²* was classified as eminently suitable for use in the dental applications.

- ISO 6872:2008, Dentistry - Ceramic materials (FDA Recognition # 4-178)

Part of Table 4 of Section 13: Test results.				
Requirements ISO 6872 (Clause)	Short description	Required value	Required value	Passed / Failed
Uniformity of the material (Clause 5.1)	Checked by visual inspection	n.a.	-	Passed
Freedom from extraneous materials (Clause 5.2.1)	Checked by visual inspection	n.a.	-	Passed
Physical and chemical properties (Clause 5.2.2)	Activity concentration of uranium 238	< 1.0 Bq/g	< 0.03 Bq/g	Passed

Part of Table 4 of Section 13: Test results.				
Requirements ISO 6872 (Clause)	Short description	Required value	Required value	Passed / Failed
Physical and chemical properties (Clause 4)	Flexural strength	> 500 MPa	> 720 MPa	Passed
Physical and chemical properties (Clause 4)	Chemical solubility	< 2000 µg/cm ²	15 µg/cm ²	Passed
Information supplied by the manufacturer (Clause 8.1.3)	Detailed Information regarding the hand- ling and treatment of the material			Passed

DD Bio ZX² (modified product) meets the requirements of ISO 6872 as well as the unmodified device. Compared to the legally marketed unmodified device the DD cubeX² (modified device) has the same high resistance against tension and pressure. The only difference to the unmodified device is the amount of yttrium contained in *DD cubeX²* and which does not raise new performance or safety issues.

Substantial Equivalence Conclusion

Dental Direkt GmbH believes that *DD cubeX²* and its accessories is as safe and effective as the unmodified device when used as instructed by knowledgeable and trained dental personnel. There is no change of the intended Use of the modified device and no difference in fundamental scientific technology. The modified device is made from the same materials and the performance safety and effectiveness has been verified in accordance with the above FDA recognized standards.

Dental Direkt GmbH therefore believes that DD cubeX² (modified device) is substantially equivalent to the legally marketed unmodified device.